

HOUSE BILL 364

By Hill M

AN ACT to amend Tennessee Code Annotated, Title 53
and Title 63, relative to containers for controlled
substances.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF TENNESSEE:

SECTION 1. Tennessee Code Annotated, Title 53, Chapter 11, Part 3, is amended by
adding the following as a new section:

(a)

(1) Except as otherwise provided in subdivisions (a)(2) and (3), a drug in
solid oral dosage form that is a Schedule II opioid, Schedule II stimulant, or a
Schedule IV benzodiazepine, and is prescribed or dispensed with more than
three (3) days of medication, shall not be dispensed without being in a lockable
vial.

(2) Subdivision (a)(1) does not apply when:

(A) The ultimate user requests, in writing, that the drug not be in a
lockable vial; or

(B) When the prescription is dispensed in an institutional
healthcare setting or long-term care setting, or the drug will be
administered to the ultimate user by a healthcare professional.

(3) The board of pharmacy may promulgate rules that establish
additional exceptions for circumstances in which requiring a lockable vial would
not be practicable and therefore not required.

(4) A prescribing physician may specify that a prescription for a controlled substance or a medication with pediatric fatality risks be dispensed in a lockable vial.

(b) For purposes of this section, "lockable vial" means a disposable container that:

- (1) Has special packaging as defined in 15 U.S.C. § 1471; and
- (2) Has a locking-cap closure mechanism that can only be unlocked:
 - (A) With a physical key;
 - (B) With a preset four-digit combination code;
 - (C) With a four-digit combination code that is selected by the ultimate user, the guardian of the ultimate user, or the parent or guardian of the ultimate user if the ultimate user is a minor. The four-digit combination code must be encoded in the locking cap by the pharmacy when the prescription is dispensed. In order to facilitate workflow, the pharmacy may use a universal method for establishing a combination code across multiple locations for the initial fill, and ascertain the patient's preferred combination code during the consultation. The pharmacy shall then store the patient's preferred combination code in the pharmacy's system, and use the patient's preferred combination code for subsequent refills;
 - (D) Biometrically with fingerprint, facial, or voice recognition technology; or
 - (E) With a smartphone application.

(c) The dispensing pharmacy and its personnel have no liability for any adverse consequences as a result of:

- (1) The failure of any lockable vial to prevent unauthorized access; or
- (2) Providing an ultimate user's combination code either:

(A) Online in a password protected ultimate user account; or

(B) Verbally, by telephone, after an ultimate user identity authentication procedure in which the ultimate user verbally provides the user's date of birth and either the user's motor vehicle license number or social security number.

(d) The prescribing physician, professional practice, or other organization has no liability for any adverse consequences as a result of the failure of any lockable vial to prevent unauthorized access, or a patient not being able to access medication in a lockable vial in an emergency.

(e) Manufacturers of applicable drugs sold in the state that are required to be dispensed in a lockable vial shall:

(1) Register on the pharmacy connectivity networks used for electronic billing and payment; and

(2) Develop with NCPDP, or other appropriate industry standards setting organization, electronic billing codes for lockable vials, for use in electronic billing and payment. Upon the dispensing of an applicable drug sold in the state that is required to be dispensed in a lockable vial, whether or not the prescription is third party reimbursed or cash paid by the patient, the dispensing pharmacy shall invoice the drug manufacturer of the applicable drug so dispensed for the cost of the lockable vial on their pharmacy connectivity network, using the National Drug Code and the billing code established for such purpose, and the manufacturer shall pay on invoice via the pharmacy connectivity network.

(f) The board is authorized to promulgate rules to effectuate the purposes of this section. The rules must be promulgated in accordance with the Uniform Administrative Procedures Act, compiled in title 4, chapter 5.

SECTION 2. For purposes of promulgating rules, this act shall take effect upon becoming a law, the public welfare requiring it. For all other purposes, this act shall take effect July 1, 2019, the public welfare requiring it.